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December 16, 2022

Via ECF/CM and Email

Hon. Joan N. Ericksen
District Judge, District of Minnesota
United States District Courthouse
12W U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

Hon. David T. Schultz
Magistrate Judge, District of Minnesota
United States District Courthouse
12W U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

Re: ***In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation***
MDL No. 15-2666-JNE-DTS

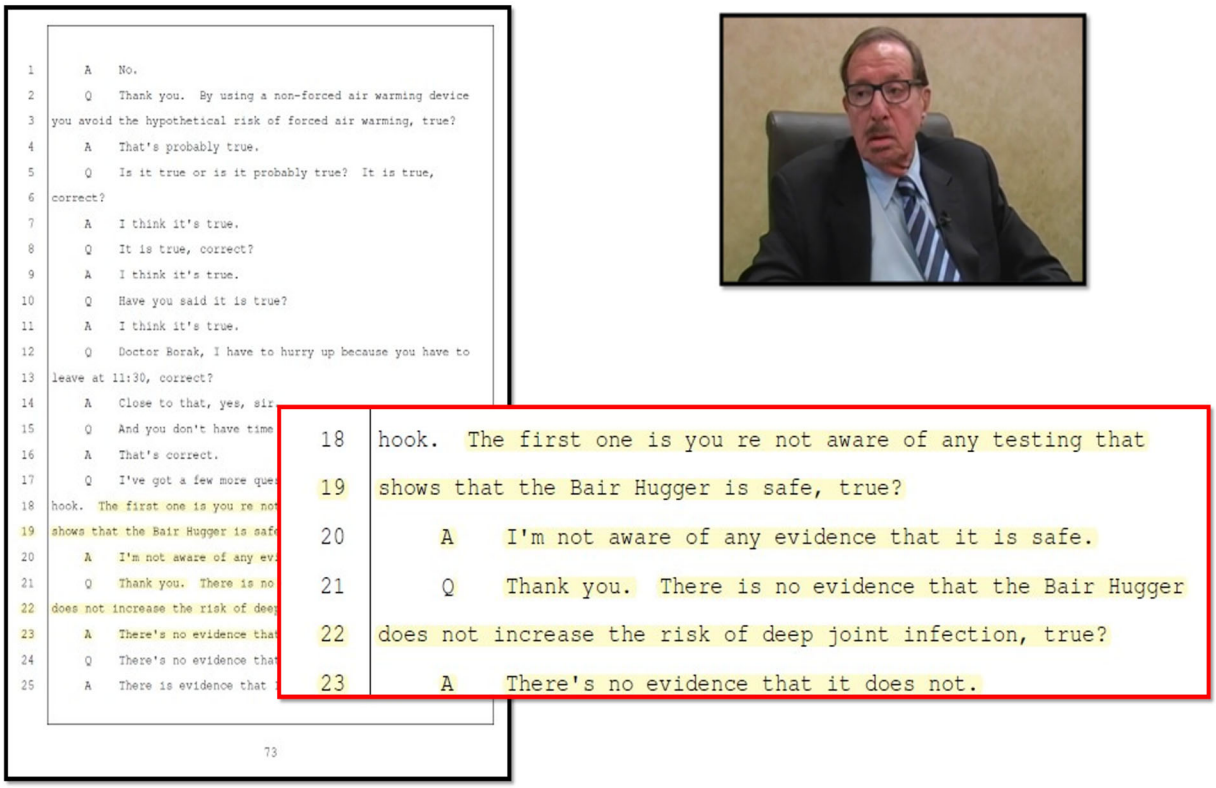
Dear Judge Ericksen and Magistrate Judge Schultz:

Plaintiffs write in response to 3M's December 14, 2022 letter. 3M's letter brief appears to be an unsolicited memorandum of law seeking modifications to existing case management orders, entry of a *Lone Pine* order, and initiation of a remand process imposing unilateral obligations on Plaintiffs and unworkable parameters for both Plaintiffs and the Court. Local Rule 7.1 not only prohibits unsolicited memoranda; it requires a meet and confer, which 3M declined to even request here. Had 3M followed the rules, the parties could have identified potential areas of agreement, narrowing the scope of disputes before the Court (e.g. discovery, remand, ongoing mediation).

As discussed in December 2021 and again in June 2022, numerous threshold and sensitive issues require careful deliberation before considering scheduling proposals such as 3M's recent submission. Indeed, the status report that the parties *jointly* submitted in January 2022—not 3M's unannounced and unsolicited proposal of this week—remains the starting point for deliberation between the Court and the parties. To the extent the Court nonetheless contemplates 3M's new proposal, Plaintiffs request an opportunity to be heard at the next in-person status conference.

In addition to its scheduling proposal, 3M attempted to "update" the Court about recent developments in this MDL. But 3M inexplicably ignores new studies, new documents, and new testimony proving that Bair Hugger causes infections in orthopedic surgeries. Rather than speculate whether the jury verdict in *Gareis* from five years ago applies to the corpus of this MDL as a whole, Plaintiffs offer the following updates that are applicable to all cases filed in the MDL:

At the *O'Haver* trial in October 2022, 3M's epidemiologist from Yale University conceded that he is "not aware of *any evidence* that [Bair Hugger] is safe," despite 3M's product-safety claims.[1]



A No.
Q Thank you. By using a non-forced air warming device you avoid the hypothetical risk of forced air warming, true?
A That's probably true.
Q Is it true or is it probably true? It is true, correct?
A I think it's true.
Q It is true, correct?
A I think it's true.
Q Have you said it is true?
A I think it's true.
Q Doctor Borak, I have to hurry up because you have to leave at 11:30, correct?
A Close to that, yes, sir
Q And you don't have time
A That's correct.
Q I've got a few more que
hook. The first one is you re not
shows that the Bair Hugger is safe
A I'm not aware of any ev
Q Thank you. There is no
does not increase the risk of deep
A There's no evidence that
Q There's no evidence that
A There is evidence that

18 hook. The first one is you re not aware of any testing that
19 shows that the Bair Hugger is safe, true?
20 A I'm not aware of any evidence that it is safe.
21 Q Thank you. There is no evidence that the Bair Hugger
22 does not increase the risk of deep joint infection, true?
23 A There's no evidence that it does not.

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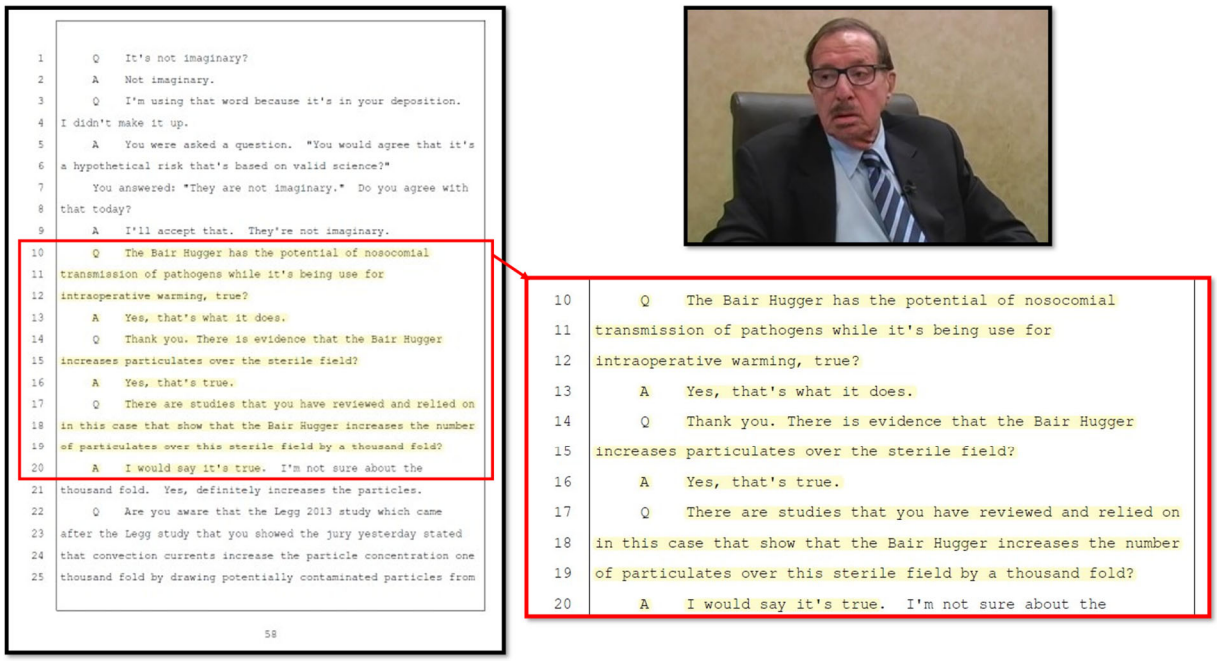
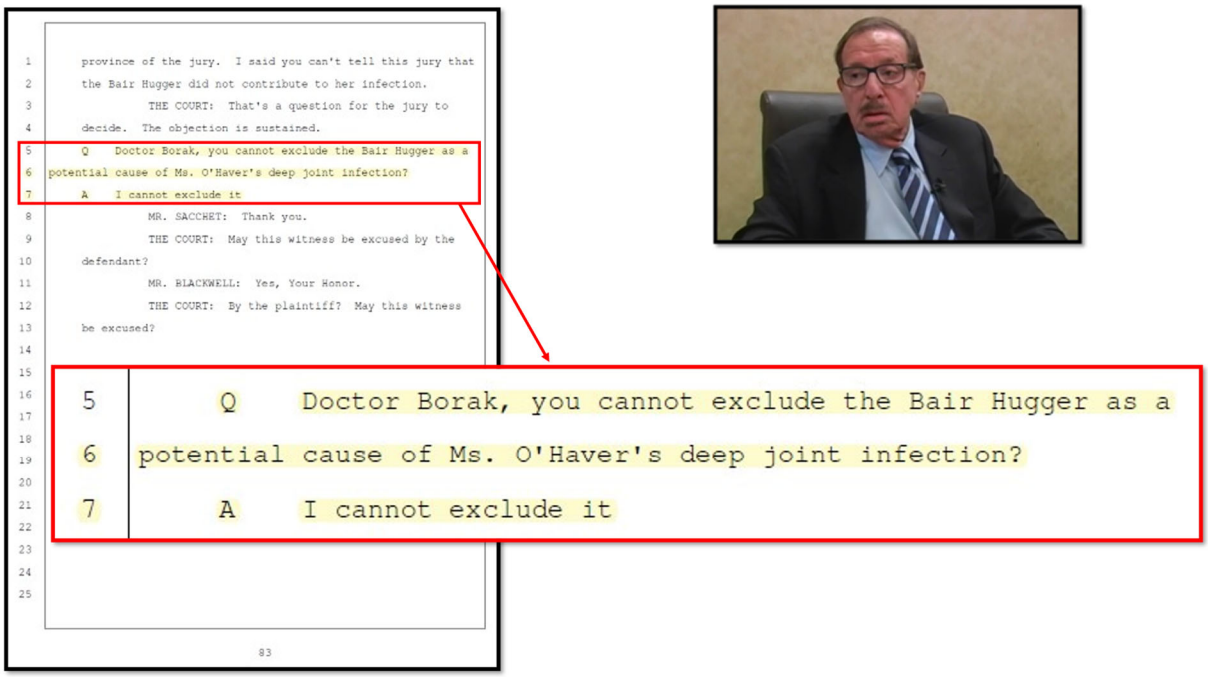
Consistent with *Plaintiff's* theory of the case, he also agreed that Bair Hugger can transmit bacteria:

[1] Unless otherwise noted, all transcript citations are to depositions and/or trial testimony in the *O'Haver v. 3M Co., Inc*. matter recently tried to verdict before Judge Jenifer Phillips in Jackson County, Missouri.



Dr. Borak even agreed that Bair Hugger was as a *potential cause* of Ms. O'Haver's infection:



These admissions doom 3M's contention that Plaintiffs' theory of specific causation were somehow "invalidated" after mediation. Dkt. 2261 at 2. One *divided* verdict—where several jurors *agreed* Ms. O'Haver proved specific causation—hardly undermined Plaintiffs' claims. Nor did Plaintiffs' leadership "handpick" *O'Haver* for trial or fraudulently sue non-diverse defendants. In truth, Ms. O'Haver not only *settled* with several of those very defendants on a confidential basis,

but the trial court agreed that Ms. O'Haver had introduced sufficient evidence to prove *punitive damages*. Further, a third case – *John Petitta v. 3M Co., Inc. and Arizant Healthcare Inc.* – was on the verge of trial in Hidalgo County, Texas. That case settled for a confidential amount last week.

In its unsolicited update letter to this Court, 3M seemingly disregards these details as well as new science, new documents, and new admissions that Plaintiffs have uncovered in 2022 alone. In response to 3M's update, Plaintiffs offer the following by way of limited relevant update:

I. NEW STUDIES SUPPORT PLAINTIFFS' CLAIMS

(1) THE LANCET (2022)

In May 2022, 3M's key opinion leader, Dr. Sessler, published a randomized controlled trial that undermines virtually all benefits 3M claims are associated with maintaining normothermia—the only purpose of Bair Hugger.[2] Given those robust findings, independent scientists have extolled the sea change in the science regarding the benefits (or lack thereof) of intraoperative warming:

> Despite widely held beliefs and guideline recommendations, in the PROTECT trial aggressive intraoperative warming did not meaningfully decrease the risk of postoperative mortality or morbidity, including myocardial injury, non-fatal cardiac arrest, intraoperative bleeding, or surgical site infection, and there were no clinically meaningful differences between the two groups in terms of adverse events. … When considered in the context of current guidelines, these findings raise the question: *how did we get it so wrong*?[3]

The PROTECT study was well known to 3M, as it was a principal funder for over two years, until 3M revoked funding half-way through the project. Documents about the PROTECT study, and 3Ms involvement with and knowledge about PROTECT while data was being collected, as well as the company's decision to terminate funding before the study was completed is certainly critically important to Plaintiffs' claims here.

(2) Lange (2022)

Earlier this year, the ANNALS OF MEDICINE AND SURGERY published a study following up on a 2018 paper which revealed that forced-air warming contamination occurs more than expected.[4] In the 2022 study, *Forced air contamination risk in the OR*, Victor Lange concludes "when FAW is

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[2] Daniel Sessler, MD, et al, *Aggressive intraoperative warming versus routine thermal management during non-=cardiac surgery (PROTECT): a multicentre, parallel group, superiority trial*, THE LANCET (April 4, 2022).
[3] Flavia K Borges & Jessica Spence, *Challenging dogma about perioperative warming during non-cardiac surgery*, THE LANCET (April 4, 2022)(emphasis added).
[4] Victor R. Lange, *Forced air contamination risk in the OR*, ANNALS OF MEDICINE AND SURGERY 73 (2022).

in use, the risk for SSI is present," and "infection risk may be eliminated through the use of alternative patient-warming technologies/techniques."[5]

(3) The Stanford Study/Brock-Utne (2021)

Another relevant development to the so-called "dirty machine" theory is a study published by Stanford University anesthesiologists who "say with certainty that the Bair Hugger is contributing airborne microbes into the [operating room] air" in a "statistically significant way."[6] According to their research, air samples from Bair Hugger hoses "contain a larger number of bacteria on average than the air coming through the OR ceiling inlets despite regularly scheduled maintenance and the use of high efficiency filters. The potential risk of blowing air containing bacteria-laden particles in close proximity to the patient and surgical site should not be underestimated."

(4) ERAS (2019)

In the fall of 2019, the *Consensus statement for perioperative care in total hip replacement and total knee replacement surgery: Enhanced Recovery After Surgery (ERAS) Society recommendations* was published.[7] ERAS then recommended maintaining normothermia, noting there are "many methods" to accomplish this goal, including prewarming. But the original ERAS Consensus Statement published online notes "the use of forced-air warming is not recommended as there is evidence that this is associate with an increased risk of infection."[8] The summary and recommendation is noted to be "Evidence level – High", and "Recommendation grade – Strong".[9]

(5) Sugai (2018)

In October 2018, *Relative Clinical Heat Transfer Effectiveness: Forced Air Warming vs. Conductive Fabric Electric Warming, A Randomized Controlled Trial* was published in the JOURNAL OF ANESTHESIA AND SURGERY.[10] Noting the "US Centers for Disease Control and Prevention recently issued a warning: 'Nothing that blows air should be in an operating theater, if possible'", the authors note the "clinical concern [of disruption of the operating room airflow and contamination of the surgical field] is especially severe in implant surgery where a single airborne

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[5] *Id.*
[6] *Warming Devices May Be Source of Airborne Microbial Contamination, but Fix is Possible,* available at www.anesthesiologynews.com (last visited October 1, 2021). See also Brock-Utne JG, Ward JT, Jaffe RA, *Potential Sources of Operating Room Air Contamination: A Preliminary Study*, JOURNAL OF HOSPITAL INFECTION (2021), https://doi.org/10.1016/j.jhin.2021.04.02.
[7] Thomas W. Wainwright et.al., *Consensus statement for perioperative care in total hip replacement and total knee replacement surgery: Enhanced Recovery After Surgery (ERAS) Society recommendations*, ACTA ORTHOPEDICA (2020).
[8] *Id.* at 10.
[9] *Id.*
[10] Haruko Sugai et al, *Relative Clinical Heat Transfer Effectiveness: Forced Air Warming vs. Conductive Fabric Electric Warming, A Randomized Controlled Trial*, JOURNAL OF ANESTHESIA AND SURGERY (2018).

bacterium can cause an infection," the authors conclude "identifying an effective air-free alternative is paramount."[11]

At bottom, while 3M has continually attempted to whitewash both the clinical and evidentiary record and continue to use 3M lawyers to make claims in courtrooms that the company knows it is not permitted to make to healthcare providers,[12] the only epidemiology study looking at the risk of developing a deep joint infection following hip or knee replacement surgery shows patients who are exposed to the Bair Hugger had a 380% increased risk of developing a PJI compared to patients warmed with an air-free alternative.[13]

II. INTERNAL DOCUMENTS

With respect to internal documents, what has also become clear is that 3M has been long engaged in a practice of manipulation and suppression of peer-reviewed literature on the subject of Bair Hugger's propensity to contribute bacterial contamination to the operating room, increasing the risk of infection in surgical patients. By way of limited example, work done in 2022 confirmed undisclosed involvement of 3M in the editing and influencing the following:

(1) International Consensus (2018):

Dr. Michael Mont is the orthopedic surgeon 3M hired at the outset of the litigation and has been paid in excess of $8,000,000 by 3M and other medical device manufactures in the past 10 years. He testified in the O'Haver trial that he edited every line of the International Consensus in 2018 while he was a paid consultant for 3M.[14]

> Q. In fact, you testified that you went through every chapter, read every line and edited every line of that International Consensus in 2018, right?
> A. Yes. I can say that I did not read every line if they offered a disclosure. So the printed word I reviewed. I didn't read everybody's disclosures if that's what you're asking me.
> A. No, no, no. You read every line of the International Consensus document, correct, Doctor?
> A. Correct.
> Q. And you offered edits to almost every portion of that entire ICOS publication, right?

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[11] *Id.*
[12] Mr. Petitta references by way of example, internal documents bearing bates numbers 3MBH00022987-3MBH00022993; 3MBH02331960-3MBH02331960.
[13] McGovern et.al, *Forced-air Warming and Ultra-clean ventilation do not mix: an investigation of theatre ventilation, patients warming and joint replacement infection in orthopaedics*, J BONE JOINT SURG BR. (2011). The MDL Court agreed McGovern "is reliable as it is published and peer reviewed." Doc. 2064 15-md-2666-JNE-DTS (7/31/19), reversed at *In re: Amador v. 3M Co., Arizant Healthcare, Inc. (In re Bair Hugger Forced Air Warming Prods. Liab. Litig.)*, --F.4th--, 2021 U.S. App. LEXIS 24255 (8th Cir. 2021)(reversing MDL Court, finding abuse of discretion and clear error in excluding plaintiffs' experts and granting summary judgment for 3M).
[14] *See* O'Haver 10/7/22 trial transcript (180:14-25).

A. Yes.

Yet Dr. Mont's status as a paid litigation consultant for 3M is never disclosed.

Dr. Mont did his editing with the Chair of the 2018 International Consensus, Dr. Parvizi. During the O'Haver trial, Dr. Bowling, Plaintiff's expert, confirmed he had reviewed the consulting agreement showing that Dr. Parvizi was being paid $5,000 a day by 3M.[15] Dr. Parvizi gave a copy of the draft International Consensus statement to 3M to review before it was published.[16] Dr. Parvizi's connection to 3M is likewise not disclosed in the 2018 ICOS.

Dr. Bowling further confirmed that in 2020, after Dr. Parvizi was no longer paid consultant of 3M, he published an article noting "These [FAW] devices should be used with caution as they may increase the distribution of aerosolized particles during the case. Blankets may be more effective at decreasing particulate generation and distribution."[17]

Finally, Dr. Bowling testified he reviewed emails demonstrating 3M's MDL trial counsel, Corey Gordon, emailed Dr. Mont asking him to make changes to the final Consensus statement.[18]

In the face of these facts there is no disclosure in the final Consensus statement of a potential conflict or bias from Dr. Mont, Dr. Parvizi or attempted influence from 3Ms MDL counsel.

(2) Memerzedeh's 2010 CFD

In various court and marketing submissions, 3M points to a CFD performed by Dr. Memerzedeh in 2010 as evidence the Bair Hugger has no impact on an operating room. But during the O'Haver trial, Dr. Yadin David confirmed that he reviewed internal 3M documents in which Dr. Memarzedeh sent an email saying his did his actual CFD calculations, not on a supercomputer like Dr. Elghoboshi, but rather during an airplane flight.[19] Much like the International Consensus, Dr. Memarzedeh sent 3M a draft of his Letter to Editor before it was sent to the journal for publication.[20]

Dr. Memerzedeh's Letter to Editor was never a peer reviewed study. Further, the clear conflict was never disclosed. Instead, Dr. Memerzedeh signed off on his Letter to the Editor noting his employment with the National Institute of Health. The implication seems to be it was an NIH sponsored study, but that's false. These are but two examples of undisclosed influence 3M has exerted on research in areas relevant to this ongoing litigation brought to light during 2022.

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[15] *See* O'Haver 9/29/22 trial transcript at pg. 180:14-25.
[16] *Id.* at 95:19-24.
[17] *Id.* at pg. 87:24-88:2.
[18] *Id.* at 95:25-96:10.
[19] *See* O'Haver 10/3/22 trial transcript at pg. 141:16-142:16.
[20] *Id.* at pg. 141:21-23.

(3) Undeveloped Facts/Additional Opportunities for Discovery

Despite representing to the court appointed discovery Special Master in O'Haver in June 2022 that it's document production was not in any way "materially incomplete", when O'Haver's motion to compel was granted, 3M found significant additional responsive documents dating back to at least 1999. Indeed, over 160,000 pages of new documents were produced in O'Haver on July 1, 2022. Another 79,000 pages were produced in O'Haver in early August. There was also a limited production in the Petitta matter. Put in context, there were less than 300,000 documents produced in the history of the MDL. Despite these 2022 productions, no depositions of 3M employees or former employees regarding these documents have taken place. Nor did 3M bring any employees or former employees to testify at trial in O'Haver.

Also confirmed during the deposition of 3M engineer Dr. Andrew Chen is the fact that 3M conducted a CFD study in 2015. Portions of the study were conducted at Fairview Southdale Hospital, pursuant to arrangements made by counsel for Fairview. Dr. Abraham, 3Ms testifying expert in CFD, was present for some of this work. 3M refuses to share the results of the 2015 CFD, citing attorney-client privilege and work product protections.

III. New Admissions from Depositions and Trial in 2022

(A) Bair Hugger is "Largely Ineffective" for Surgeries Under One Hour, Any Benefits to Warming "Exceedingly Hard to Prove" for Low-Risk Surgeries such as THA/TKA, and Bair Hugger Not Indicated for Use with Obese Patients

Plaintiffs have also taken depositions in 2022 that have resulted in critical admissions relevant to this MDL. By way of example, 3M knows that the Bair Hugger is *largely ineffective* for at least the first hour of an operation.[21] 3Ms expert in orthopedic surgery agrees most total hip and knee replacement surgeries take on average 45 minutes.[22] 3M admits that joint replacement surgeries have very low complication rates, and for surgeries with very low complication rates the evidence for benefit of forced-air warming is less clear and exceedingly difficult to prove.[23] 3M agreed that if a medical device has no benefit, that any risk associated with the product is unreasonable.[24] 3M

[21] Transcript of Al Van Duren (1/25/22, 74:10-22) (Q. Intraoperative warming is largely ineffective for the first hour of an operation. That's a true statement correct? A. At minimizing the reduction in core temperature. Q. But that's what the Bair Hugger is meant to do, correct? A. Yes. **So it's largely ineffective for what it's mean to do for the first hour? A. It can be, yes**. Q. All right. You knew that as far back as 2005, 2008, correct? A. Probably).

[22] Deposition of Dr. Michael Mont, 3/31/22 (*Hand vs. Smith & Nephew,* D.Md.)

[23] Transcript of Al Van Duren (1/25/22, 3-13).

[24] Transcript of Al Van Duren (1/25/22, 77:10-12)(Q: Right. If there's no benefit, then any risk would be unreasonable, correct? A: That's correct.)

also knows that the Bair Hugger is ineffective at warming obese patients,[25] yet has never provided a warning it is not for use with obese patients.[26]

(B) No Study Conducted Despite World-Wide Questions and Complaints for Decades

Depositions taken in 2022 confirm the truth is that 3M and its predecessor companies had been receiving questions and complaints about Bair Hugger as the potential source of bacteria and airborne transmission of contamination that causes infection since at least the early 1990s.[27] Further, and perhaps more importantly, 3M has been aware of the concerns raised by both clinicians and by Dr. Augustine since the time the company conducted its due diligence prior to acquiring the predecessor company, Arizant. 3M certainly knew who Dr. Augustine was, and to the extent his 2004 guilty-plea to a charge related to Medicare fraud was relevant, the onus was properly on 3M to take a particularly critical look at the product developed by someone the company now casts as a crook and a fraudster to be sure that the product line it was acquiring for nearly $1 Billion in 2010 was in fact safe, effective, and provided clinical benefits to surgical patients that outweighed the risk associated with use of the Bair Hugger. Instead, 3M closed its corporate eyes, purchased the company, and has refused to conduct safety testing the medical community has been begging for to this day.

Despite the questions and concerns from clinicians around the world,[28] through 2022, neither 3M nor any of its predecessor companies performed any testing or other activities to determine whether there is merit to these customer concerns.[29] In fact, 3M recognizes that any medical device to be used in an operating room should consider whether the device causes airborne contamination,[30] yet nearly 35 years after the Bair Hugger was first sold, even in 2022 3M is unaware of any investigation or testing done to determine whether the Bair Hugger affected the operating room.[31]

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[25] Transcript of 3M (4/14/22, 311:6-8)(Q. But also If a patient isn't going to become cold because they are obese, there's also no benefit to using the Bair Hugger, fair? A. Yes, I would agree with that.)

[26] Transcript of 3M (4/14/22, 310:12-19)(Q. **So if obese patients don't get cold**, is there a warning or a precaution on the Bair Hugger at all saying you don't need to use this with obese patients? A. No. Q. Why is that? **A. Well, it's not contraindicated. It's just not indicated, because it's not necessary.)**

[27] Transcript of 3M (4/14/22, 251:18-252:2)(Q. Sure. So when you started at the company in 1994, you were already told that there were customers calling in with either questions or complaints about the potential risk of wound infection coming from airborne contamination associated with the Bair Hugger? A. So there was some questions about it, yes, in 1994).

[28] Transcript of AVD (1/25/22, 40:9-12)(Q. It's fair to say that you had complaints or questions coming in worldwide. It wasn't just in the United States, right? A: I suspect that they were worldwide, yes.)

[29] Transcript of 3M (4/14/22, 36:16-37:5)(Q. Do you recall what, if anything, Augustine Medical or Arizant or 3M did to determine whether any of these issues of airborne contamination were actually true or not? A. **I'm not aware of any activities done to confirm the suspicions that there were problems associated with that**. Q. Were there any activities to confirm that the opposite is true, that there is no airborne contamination? A. **I'm not aware of any activities that were done to confirm the opposite.** Q. Okay. And when you say "you," you mean 3M, correct? A. 3M).

[30] Transcript of 3M (4/14/22, 74:7-11)(Q. Another factor that should go into the design of a medical device that is used in an OR is whether or not it would cause any type of airborne contamination, correct? A. Yes)

[31] Transcript of 3M (4/14/22, 50:17-23)(Q. What did Augustine Medical do, when they existed, to determine whether or not the 500 OR had any affect on the ability of an operating room to reduce particulates over the sterile field? **A. I don't know that anything was done to investigate that.)**

This despite the fact that 3M admits that ever single study shows an increase in particulates over the sterile field when the Bair Hugger is used.[32] 3M has no data to refute that.[33]

3M has long been aware there is a relationship between the number of particles over the surgical site and the risk of infection in an orthopedic surgery.[34] Likewise, 3M has known for years there is amazing concern in the orthopedic surgeon community about particulates in the air during joint replacement surgery.[35] In fact, the experts 3M brought to the *O'Haver* trial testified under oath that the majority of squames carry bacteria.[36] And while 3M agrees that people in the hospital rely on medical device manufacturers to tell them about risks and benefits of the products the company manufactures,[37] no warnings about the risk of infection or airborne contamination have been included on any Bair Hugger cleared by the FDA for use in the operating room.

(C) Decisions Not to Conduct Safety Studies Made "At a High Level"

What did Augustine Medical, then Arizant, and now 3M do when faced with world-wide questions and complaints about the Bair Hugger? Dr. Michelle Hulse-Stevens 2016 deposition was played at the O'Haver trial. She confirmed "G**iven the ongoing legal situation, decisions were made**

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[32] Transcript of 3M (4/14/22, 132:13-17)(Q. Yes. Okay. And 3M is aware that every single study that looked at this issue shows an increase of particulates in absolute numbers when the Bair Hugger is used, correct? A. Yes.)

[33] Transcript of 3M (3/7/17, 258:5-13)(Q. Based on the data that we have today, including the study funded by 3M as well as other studies, **every single study indicates that the Bair Hugger increases the particle count over the sterile field**; correct? A. In absolute numbers, yes. Q. … And you have no internal studies to refute that; correct? A. No, we don't.); Transcript of Al Van Duren (1/25/22, 47:20-48:12)(Q. ... and the question was: "Okay. Based on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field; correct? And you answered, "In absolute numbers, yes." It says - the question is: "Yes. Okay. And you have no internal studies to refute that; correct?" The answer is: "No, we don't." That was an accurate statement that you gave in 2017, correct? A. It was. Q. As far as you know today, is that still an accurate answer? A. To my knowledge.)

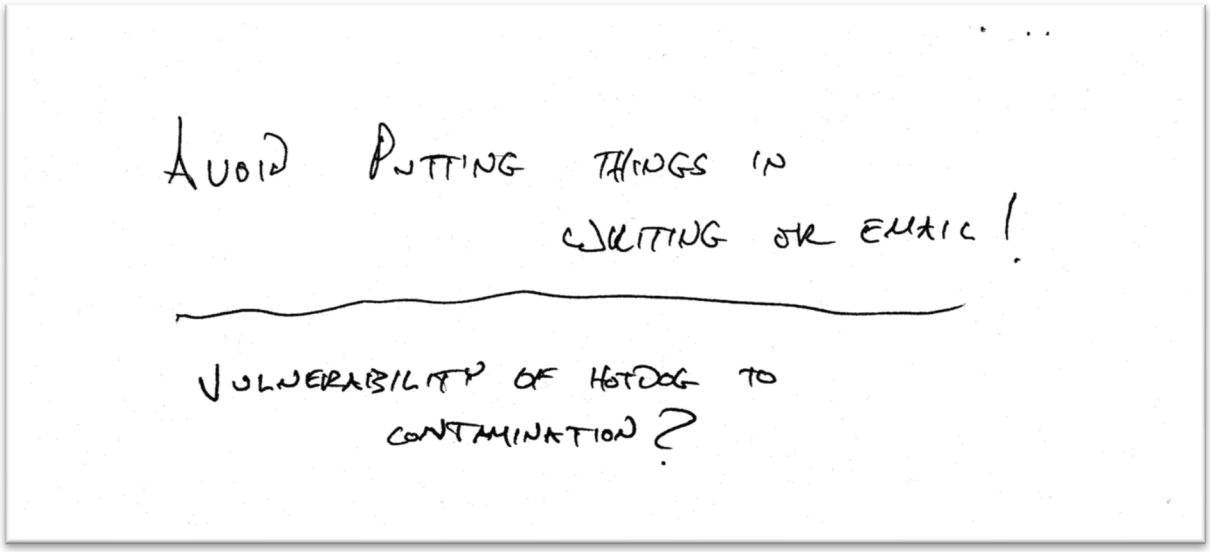
[34] Transcript of 3M (2/3/22, 56:10-14)(Q. 3M is aware that there's a relationship between the number of particles over the surgical site and the risk of infection in an orthopedic surgery? A. Yeah, we are aware of that.)

[35] Transcript from O'Haver trial, (10/6/22)(playing deposition of Dr. Michele Hulse-Stevens, 60:24-61:22)(Q. And you sat in on a group addressing the OR environment at this International Consensus meeting; didn't you? A. Right. Q. And you found out that there was **amazing concern about any particulates in the air during joint-replacement surgery**; correct? A. I'm going to just read through this email, if you could give me a second to do that. Q. Sure. A. Okay. Q. **You found there was an amazing concern about any particles in the air during joint-replacement surgery; correct?** A. I had never sat in with a group of orthopedic surgeons before and listened to their dialogue about this particular aspect of their work, and I was struck by how concern they had - how much concern they had about particulates. Q. And there was amazing concern, as you described it, correct? A. That was my takeaway from that meeting.)

[36] Transcript from O'Haver trial, (10/7/22, 60:14-19)(Dr. Borak)(Q: Under oath you were asked the question: 'Well when he says that the majority of squames carry bacteria, you are not going to disagree with that, correct?' Your answers under oath: 'I won't go out and disagree with that, no.' Is that what you said? A: That was [3M infectious disease expert] Dr. Anderson's testimony. I do not disagree.").

[37] Al Van Duren deposition, (:3-11)

previously (at a high level) not to pursue clinical research on this topic.[38] And of course we know there was a longstanding policy not to put things in writing or email:



This testimony is relevant to questions of both general and specific causation for all cases pending in this MDL.

(D) Internal Documents Confirmed Knowledge of Risk and Safer Alternatives No Later than 2005

There are and have been for many, many years multiple different modalities available to clinicians in the event they elect to warm surgical patients. One of the options is prewarming a patient, which can be accomplished with identical convective technology simply before the operation begins. The so called "Bair Paws" or "Prewarming" documents, which had been submitted in support of various dispositive motions in the MDL, resurfaced as well. When asked about these documents during non-confidential depositions conducted in the O'Haver case in 2022, Mr. Van Duren confirmed that the Bair Paws documents contain no trade secrets[39] and further, that the clinical trial protocols were sent outside 3M in 2007 to multiple people.[40] "Bair Paws" 2005 and 2007 documents were admitted, unredacted, during the O'Haver trial.[41] Plaintiff's expert orthopedic surgeon, Dr. Bowling, confirmed that the Bair Paws memos contain a Pros/Cons and Advantages/Disadvantages chart where, on behalf of the company, Mr. Van Duren compared convective prewarming to convective intraoperative warming. Specifically, he testified that Mr. Van Duren's memorandum stated the following are advantages of prewarming when compared with intraoperative forced air warming:

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[38] Deposition of Dr. Michelle Hulse-Stevens, (12/19/2016)(252:12-254:12)(emphasis added).
[39] Deposition of Al Van Duren at (277:1-278:6)
[40] *Id.* at (277:15-279:8)
[41] See PX1759 (2005); PX903 (September 6, 2007) from O'Haver trial.

1. Can be used when intraoperative warming is contraindicated such as aortic cross clamp and orthopedic cases
2. Does not contaminate sterile field
3. Effective during the first hour
4. Reduces the incidence of surgical site infection
5. Reduces the potential for nosocomial transmission of pathogens by eliminating the need for intraoperative warming.[42]

Not surprisingly, Dr. Bowling confirmed these are risks that he, as an orthopedic surgeon, would expect a reasonable medical device company to warm about. Yet this is information that 3M has successfully shielded from disclosing to the medical community and the public for years.

IV. CONCLUSION

Indeed, the only times that a court has ruled on issues with respect to specific causation, the case survived both summary judgment and directed verdict. Put another way, 100% of the cases where allegations with respect to specific causation was considered by courts, the court has agreed that plaintiff offered sufficient evidence on the specific causation question. If the Court were to graft past results on to the corpus of the cases in the MDL, what we know is every case that made it that far met the threshold requirements to get to a jury on specific causation. Given these facts, 3Ms request for premature summary judgment and a *Lone Pine* order is shocking.

To conclude, Plaintiffs note our belief there remain threshold issues that require discussion and deliberation as to next steps in the MDL. Further, we object to 3Ms impermissible attempt to impose unilateral obligations on Plaintiffs through suggested modifications to existing CMOs and a request for *Lone Pine* and/or expedited summary judgment decisions by letter brief. The Federal Rules of Civil Procedure and the Local Rules for the District of Minnesota provide an adequate framework for such requests, and we respectfully request the Court direct the rules be followed.

Respectfully submitted,

Genevieve M. Zimmerman

GMZ/hms

cc: All counsel of record (*via ECF*)

[42] *See* O'Haver 9/28/22 trial testimony at 172:13-175:17.